

April 27, 2022

BY E-FILE

The Honorable Christopher J. Burke
United States District Court of Delaware
844 North King Street
Wilmington, DE 19801

Re: *Sysmex Corp. & Sysmex America, Inc. v. Beckman Coulter, Inc.* No. 1:19-cv-01642-RGA-CJB

Dear Judge Burke:

On behalf of our client, BCI, we write to request a stay of this action. The parties have agreed to follow the Court's most recent Model Scheduling Order in connection with this motion.

The Court should stay this action because the facts determined in a Final Written Decision ("FWD") issued in an *Inter Partes* Review ("IPR") between the parties are case dispositive. (Ex. 1.) The PTAB determined, **as a fact**, that the specification for the asserted patents does not contain "adequate written description" for a controller programmed to sense white blood cells in body fluid using an electrical detector. (*Id.* at 26.) It is undisputed that BCI's accused machines use this arrangement. Therefore, the PTAB's finding necessarily establishes **as a fact** that the asserted claims lack adequate written support for their full scope.

Sysmex had two months to file its appeal, *see* 35 U.S.C. § 142, but **it waited until April 20, 2022**, just two days prior to the deadline, to file its notice. (Ex. 2). The next day, BCI asked Sysmex whether it would agree to stay this action pending appeal, or, in the alternative, whether it would stipulate to the PTAB's factual determinations. (Ex. 3.) Sysmex would not schedule a conference until today, April 27, 2022. (*Id.*) BCI would have sought a stay months ago if Sysmex had promptly filed its notice of appeal and timely cooperated with BCI.

I. Legal Standard

This Court considers the following three factors to determine whether a stay is appropriate: (1) whether a stay will simplify the issues for trial, (2) whether discovery is complete and a trial date has been set, and (3) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party. *See AgroFresh Inc. v. Essentiv LLC*, No. CV 16-662 (MN), 2019 WL 2327654, at *1 (D. Del. May 31, 2019).

II. Background

In November 2017, BCI accused Sysmex of infringing a patent in an action now pending in Illinois. Although Sysmex had several patents at its disposal, it did not counter-assert any. Instead, it went back to the USPTO to obtain the patents-in-suit through accelerated applications. (Ex. 4, 5.) Sysmex then filed this retaliatory lawsuit on September 3, 2019, the day the patents issued. (D.I. 1.) The patents-in-suit claim priority to a January 31, 2008 application, *see* Ex. 1 at 13, which preceded BCI's launch of the accused products by less than a year, *see* Ex. 6. For more than a decade, Sysmex had kept alive a chain of "continuation" applications claiming priority to that original 2008 application, which it used in 2019 to obtain the asserted claims.

More specifically, claims 7–15 of the '351 patent, which Sysmex initially asserted against BCI, recited electrical detectors for sensing white blood cells. These cells, as recognized by the Court, can include "mono-nucleated cells and poly-nucleated cells." (D.I. 230 at 18, 28–33.)

Although the accused products use this arrangement, it is not described by the patent specification. Instead, the specification exclusively describes using optical detectors to count white blood cells in body fluid. (Ex. 1 at 27.)

In its FWD, the PTAB agreed with BCI: “[W]e find that the priority applications do not contain adequate written description for a controller programmed to analyze the cells in a body fluid measurement sample that were sensed by an electrical detector, and to count the mono-nucleated cells and poly-nucleated cells.” (Ex. 1 at 26.)

III. The Asserted Claims Are Invalid for Lack of Written Description

Each asserted claim requires sensing cells in body fluids, but none specifies the type of detector and many do not specify which cells are counted. Sysmex asserts that the claims generically cover any detectors for counting any cells in body fluid. (D.I. 407 at 36.) According to Sysmex, the scope of the asserted claims is broad enough to cover the accused DxH products, which use electrical detectors for sensing white blood cells in body fluid. (D.I. 416 at Ex. 11 ¶¶ 88, 142 (accusing body fluid mode of separately counting mononuclear and polynuclear white blood cells based on “electrical signals.”), 234; D.I. 416 at Ex. 13 ¶ 50 (accusing BCI’s body fluid mode of counting cells electrically but its blood mode of counting cells optically and electrically).)

The FWD establishes that the specification does not have adequate written description for claims of this scope. The asserted patents “do not reasonably convey to a POSA that the inventors were in possession of a sample analyzer that both (1) uses an electrical detector to electrically sense cells in a body fluid measurement sample, and (2) from the analysis of the cells sensed by the electrical detector, counts the number of mono-nucleated cells and polynucleated cells in the body fluid measurement sample.” (Id. at 17.) “Specifically, we find that the priority applications do not contain adequate written description for a controller programmed to analyze the cells in a body fluid measurement sample that were sensed by an electrical detector, and to count the mono-nucleated cells and poly-nucleated cells.” (Id. at 26.) **These are all factual determinations.** See *Rivera v. Int’l Trade Comm’n*, 857 F.3d 1315, 1319 (Fed. Cir. 2017) (adequacy of written description is “a question of fact”).

This is a fundamental problem for Sysmex. Its patent specification describes the way Sysmex measures body fluid, which is different from how BCI does it. This technology mismatch is almost certainly the reason why Sysmex did not attempt to patent BCI’s configuration prior to 2019. Sysmex did not have possession of BCI’s configuration in 2008. It was only after BCI sued that Sysmex broadened its patents. But generic claims that broadly cover all detectors for sampling all cells in body fluid is not a legally valid option. In *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1478–80 (Fed. Cir. 1998), the patentee amended the claims to remove a previously recited limitation (placement of recliner controls between two recliners), but the broader claims lacked adequate written description and were invalid because the specification indicated possession of only a much narrower invention. *Id.* Likewise, in *Lizardtech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345–46 (Fed. Cir. 2005), claims to a generic method lacked adequate written description because the specification taught only one particular method and there was no evidence that the specification contemplated a more generic method. In these cases, the applicant did not show possession of the invention as broadly claimed. This District Court has reached similar conclusions. *Pernix Ireland Pain DAC v. Alvogen Malta Operations Ltd.*, 323 F. Supp. 3d 566, 628 (D. Del. 2018) (“Therein lies the written description problem: the claims are far broader than the disclosure.”). Sysmex did not invent using all types of detectors for sensing all types of cells in body fluids, and its patent specification does not demonstrate that its inventors had possession of such a broad invention. What is claimed by a patent and what is disclosed in the specification “must be the same.” *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1347 (Fed. Cir. 2010). Because that is not the case here, the asserted claims are invalid. The specification, **as**

a matter of fact, does not support the asserted claims. *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1303, 1307 (Fed. Cir. 2008) (because priority application described only one of two different user interface options, a claim generic to both options lacked written support).

The FWD, if affirmed by the Federal Circuit, will have preclusive effect for all issues litigated to finality. *XY, LLC v. Trans Ova Genetics*, 890 F.3d 1282, 1294 (Fed. Cir. 2018). Affirmance also is the most likely outcome from the appeal. (Ex. 7.) The parties should not have to argue, and the jury should not have to decide, the written description inquiry at trial when the Federal Circuit will already address the PTAB's factual determinations.

IV. A Stay of this Action Is Necessary to Avoid Undue Burdens

Trial is presently scheduled for June 27, 2022, and the parties are to submit a proposed pretrial order by May 27, 2022. If a trial moved forward in the current posture, BCI would press its written description and related non-enablement defenses to the jury. Sysmex would oppose those defenses. The jury therefore will be asked to decide the same facts that the PTAB has already decided. If a trial occurs prior to the appellate decision, the jury's work may be undone by a subsequent Federal Circuit decision. Any inconsistency between the jury's factual findings and the Federal Circuit's decision will necessitate a second trial. There is no reason to force members of the public to sit in trial only to reach a verdict that must be vacated. In *AgroFresh*, this Court granted a stay pending an anticipated appeal of a PTAB decision even when "fact and expert discovery [we]re complete and summary judgment motions ha[d] been filed." 2019 WL 2327654, at *2. That is what the Court should do here. It is hard to envision a more inefficient situation than for the Court, a jury and parties to try this case to a verdict, only to have the Federal Circuit later undo that verdict because the claims are invalid and cannot be infringed. *Id.*; see also *Sound View Innovations, LLC v. Walmart Inc.*, No. 19-660-CFC-CJB, 2019 WL 7067056, at *4-5 (D. Del. Dec. 23, 2019) (staying proceedings due to the potential for conflicting decisions reached by the Court and the Federal Circuit); *Intuitive Surgical, Inc. v. Auris Health, Inc.*, No. 1:18-cv-01359-MN (D. Del. March 23, 2021), D.I. 424 (staying case with respect to a patent due to an appeal) (attached hereto as Ex. 8.) No matter how far a case has progressed, courts have issued stays to save judicial resources and avoid inconsistent outcomes. See, e.g., *Ultratec, Inc. v. Sorenson Commc'ns, Inc.*, No. 13-CV-346-BBC, 2015 WL 2248437, at *1 (W.D. Wis. May 13, 2015) (staying case post-verdict).

V. A Stay Will Not Unduly Prejudice Sysmex

Sysmex did not have to take an appeal at all. It could have accepted the FWD and moved forward with this case. It also could stipulate to the PTAB's factual determinations, **which Sysmex has no reason to avoid doing if it believes they are not relevant to this case**. Sysmex has a right to appeal, of course, but a stay of this action is the necessary consequence of its choice.

Nor does the parties' relationship as competitors demonstrate that a stay is unwarranted. Here, the accused products have been on sale since December 2008. Sysmex waited more than a decade to draft claims that it could assert against these products, which confirms an absence of prejudice. Even assuming Sysmex could articulate some harm, "there comes a point at which any prejudice to the Plaintiff[s] in staying the litigation is significantly outweighed by a determination that patent claims are invalid by the expert agency in the field." *Motion Games, LLC v. Nintendo Co.*, No. 6:12-CV-878-RWS-JDL, 2015 WL 13404313, at *1 (E.D. Tex. June 8, 2015) (internal quotation marks omitted). And "at that point, any further expenditure of party or judicial resources on invalid claims is unwise," particularly as "a substantial amount of pretrial, trial and post-trial resources have yet to be expended." *Id.* Pending the Federal Circuit's determination on an issue that essentially disposes of the case in its entirety, a stay of the proceedings is the proper outcome.

Young Conaway Stargatt & Taylor, LLP

The Honorable Christopher J. Burke

April 27, 2022 - Page 4

Respectfully,

/s/ Melanie K. Sharp

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